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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/791,219	03/02/2004	Lois Weisman	IOWA:048US	3887

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EXAMINER	
LIU, SAMUEL W	
ART UNIT	**PAPER NUMBER**
1653	

DATE MAILED: 08/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/791,219	WEISMAN, LOIS	
	Examiner	Art Unit	
	Samuel W. Liu	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-60 is/are pending in the application.

4a) Of the above claim(s) none is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-60 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Restriction to one of the following inventions is required under 35 U.S.C. 121:

1. Claims1-15, drawn to an isolated polynucleotide and a host cell comprising a vector comprising the polynucleotide, are classified in class 536, subclass 23.1, and class 435, subclasses 69.1 and 320.1.

2. Claims 16-26, drawn to an isolated polypeptide, are classified in class 530, subclasses 324, 326, 333 and 344, and class 514, subclasses 12 and 13.

3. Claims27-28, drawn to an antibody, are classified in class 530, subclass 387.1

4. Claims 29-32, drawn to a non-human transgenic animal comprising an expression vector comprising the polynucleotide, are classified in class 800, subclass 13.

5. Claims 33-58, drawn to a method of identifying a subject of developing diabetes comprising assessing biological structure and function and expression in cells of said subject, are classified in class 514, subclass 2.

6. Claims 59-60, drawn to a method of screening a candidate compound of ability of increasing glucose uptake comprising providing a insulin-responsive cell, contacting the cell with the compound and measuring PIP_2 level in the cell, are classified in class 435, subclass, 4, class 530, subclass 303, and class 514, subclass 2.

The inventions are distinct, each from the other because of the following reasons:

Inventions 1, 2 and 3 are patentably distinct from one another because of the materially different structures of the compounds claimed. The Invention 1 is drawn to polynucleotide and Invention 3 to an antibody while Invention 2is drawn to a polypeptide. The biopolymer that are

the subject of each group are independent and/or patentable distinct from each other because each biopolymer is structurally distinct. The biopolymers of each invention would be expected to exhibit different physical and chemical properties, and are capable of separate manufacture or use.

In addition, Invention 1 is directed to polynucleotides that is classified in class 536, subclass 23.1, and/or to a cell into which polynucleotides is transferred and a vector where the polynucleotide is bale to directing biosynthesis of the gene product, which process would have been searched in class 435 subclass 69.1. Invention 3 is directed to antibody that is classified in class 530, subclass 387.1. Thus, they acquire the different classification.

Invention 1 (polynucleotide) and Invention 3 (antibody) are distinct from each other because of the materially different structures of the compounds claimed. The Invention 1 is drawn to polynucleotide, whereas Invention 3 is drawn to immunoglobulin. The biopolymers that are the subject of each group are independent and/or patentable distinct from each other because each biopolymer is structurally distinct. The nucleic acid is composed of deoxyribonucleotides linked by phosphodiester bonds and forms a double helix as a stable conformation while antibody is composed of amino acid residues linked by peptide bonds. Thus, biopolymers of each invention would be expected to exhibit different physical and chemical properties, and are capable of separate manufacture or use.

Inventions 2 (polypeptide) and Invention 3 (antibody) are distinct from each other because of the materially different structures of the compounds claimed. Although antibody is belong to a types of polypeptide, antibody is glycosylated and its tertiary structure is unique, where four subunits (2 light chains and 2 heavy chains) associate via disulfide bonds into a Y-shaped symmetric dimer. Thus, the macromolecule of each invention would be expected to exhibit different physical and biochemical properties, and are capable of separate manufacture or use.

Inventions 1, 2 and 3 are patentably distinct from the multicellular product (transgenic non-human animal of Invention 4. The transgenic animal is living organism which function and

biochemical properties are distinct from the product of Inventions 1-3. The composition of each invention would be expected to exhibit different physical/physiological and chemical/biochemical properties, and are capable of separate manufacture or use.

Invention 1 is related to Invention 5 as product and process of use because assessing the expression in the method of Group 5 involves the polynucleotide (Group 1) directed protein biosynthesis/expression. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the polynucleotide (Group 1) directed polypeptide (Group 2) biosynthesis/expression can be used in hybridization assay, for example.

Invention 1 is unrelated to Invention 6. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, invention 6 does not require use of the polynucleotide of Group 1 in the screening method of Group 6; and mode of action of DNA involved hybridization is distinct from that of the screening method.

Invention 2 is related to Invention 5 as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the polypeptide (Group 2) can be used in proteinchip array to investigate signal transduction pathway in which the polypeptide involves, for example.

Invention 2 is unrelated to Invention 6. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, invention 6 does not require use of the polypeptide of Group 2 in the screening method of Group 6; and mechanism of polypeptide involved action, e.g., protein-protein interaction is distinct from that of the screening method.

Invention 3 is unrelated to Inventions 5 and 6. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, inventions 5 and 6 do not require use of the antibody of Group 3; and mechanism of immunological reaction of the antibody is distinct from that of the screening method.

Invention 4 is unrelated to Inventions 5 and 6. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, inventions 5 and 6 do not require use of the transgenic animal for the screening assay thereof; and reproductive property of the transgenic animal lacks in the mode of action of Groups 5-6 methods.

Inventions 5-6 are directed to related methods. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the Groups 5-6 are directed to different methods, assessing biological structure/function in the Group 5 method is not required in the Group 6, vice verse the measuring a signaling molecular (e.g., PIP_2) of Group 6 is not required for the Group 5 method

Additional Election

Applicant is required under 35 US 121 (1) to elect a single disclosed composition to which claims are restricted.

• If Group 1 is elected, applicant is required to elect one polynucleotide with the sequence identifier from claims 1-10 and 13 because the polynucleotides encoding the polypeptides of SEQ ID NOs: 1, 3, 5 and 7 are structurally distinct from one another.

• If Group 2 is elected, applicant is required to elect one polypeptide with the sequence identifier from claims 16-24 because the polypeptides of SEQ ID NOs: 1, 3, 5 and 7 are structurally distinct from one another.

• If Group 3 is elected, applicant is required to elect one antibody which specifically recognize one polypeptide as mentioned above from claims 27-28.

• If Group 3 is elected, applicant is required to elect one non-human transgenic animal from claims 29-32; said animal comprises one nucleotide sequence having the above-mentioned polynucleotide.

• If Group 5 is elected, applicant is required to elect one polypeptide expressed in the claimed cells from claim 33.

It is noted that this requirement is NOT to be construed as a requirement for an election of species, but rather additional election under 35 US 121, since each polynucleotide or polypeptide set forth in the claims are patentably distinct in structure (nucleotide or amino acid sequence) and/or biological function; and thus, is not a member of single genus of invention.

Because these inventions are distinct for the reasons given above and since they have acquired a separate status in the art shown by their different classification and/or divergent subject matter, and/or are separately and independently searched, restriction for examination purposes as indicated is proper.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the

application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel Wei Liu, Ph.D. whose telephone number is (571) 272-0949. The examiner can normally be reached Monday-Friday 9:00 -5:30. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber, can be reached on (571) 272-0925. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communication and (703) 305-3014 for the after final communication.

Samuel W. Liu, Ph.D.
July 31, 2006

KAREN COCHRANE CARLSON, PH.D
PRIMARY EXAMINER